

II. REMARKS

Formal Matters

Claims 1, 2, and 6-21 are pending after entry of the amendments set forth herein.

Claims 1, 2, and 6-19 were examined and were rejected.

Claims 20 and 21 are added. Support for new claims 20 and 21 is found in the claims as originally filed, and throughout the specification, including the following exemplary locations: Examples; paragraphs 0084-0098; and Figure 4. Accordingly, no new matter is added by these new claims.

Applicants respectfully request reconsideration of the application in view of the remarks made herein.

Withdrawal of previous rejection

Applicants note with gratitude that the rejection of claims 1, 2, and 6-17 under 35 U.S.C. §103(a) over Yang in view of Kumar has been withdrawn.

Rejection under 35 U.S.C. §103(a)

Claims 1, 2, and 16-19 were rejected under 35 U.S.C. §103(a) as allegedly unpatentable over Yang et al. ((1997) *Vaccine* 15:1303-1313; “Yang”) in view of Kumar et al (April, 2002) *Immunology Letters* 81:13-24) and Bujard et al. (WO 98/14583; “Bujard”).

The Office Action stated: 1) Yang teaches a recombinant vaccinia virus encoding a *Plasmodium falciparum* merozoite surface antigen (MSA1); 2) Yang does not teach that the recombinant vaccinia virus merozoite surface protein-1 (MSP-1) protein is from the 3D7 or FCB1 strain of *P. falciparum*, or an MSP-I with reduced AT content; 3) Kumar teaches a DNA plasmid vaccine encoding MSP-I from the 3D7 strain of *P. falciparum*; and 4) Bujard teaches a *Plasmodium* species that is stabilized by a process characterized by a reduction of the AT content. The Office Action also stated that a Modified Vaccinia Ankara (MVA) was developed as an expression vector, citing Yang. The Office Action concluded that the combination of references teaches the claimed invention. Applicants respectfully traverse the rejection.

Yang discusses a recombinant vaccinia virus that comprises sequences encoding various C-terminal fragments of *P. falciparum* MSA1. Yang merely mentions MVA in the context of concerns

regarding the safety of live vaccinia virus as a vaccine vector. In this context, Yang merely states that a “highly attenuated strain of vaccinia virus, Ankara (MVA), has been developed as an expression vector and shown to be equivalent to replication competent vaccinia virus in several vaccine models.” Yang, page 1311, column 2, last paragraph.

The MVA vector is a highly attenuated vector. It is well established in the art that MVA is a strongly attenuated vector which typically involves use of an adjuvant when using MVA as a vector. In particular, an immune response to malaria antigen generally requires adjuvant use. Yang, bridging sentence pages 1311-1312.

In contrast to the prevailing view in the art, it was shown that a vaccine preparation comprising a subject recombinant MVA virus was effective in inducing a humoral immune response *in the absence of an adjuvant*. See, e.g., instant specification, paragraphs 0084-0098; and Figure 4. Such a result would not have been predicted from the cited art.

Conclusion as to the rejection under 35 U.S.C. §103(a)

Applicants submit that the rejection of claims 1, 2, and 16-19 under 35 U.S.C. §103(a) has been adequately addressed in view of the remarks set forth above. The Examiner is thus respectfully requested to withdraw the rejection.

III. CONCLUSION

Applicants submit that all of the claims are in condition for allowance, which action is requested. If the Examiner finds that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

The Commissioner is hereby authorized to charge any underpayment of fees associated with this communication, including any necessary fees for extensions of time, or credit any overpayment to Deposit Account No. 50-0815, order number GRUE-004.

Respectfully submitted,
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